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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,327	08/08/2001	Patricia D. Murphy	044921-5054-02	3339
9629	7590	12/15/2003	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/923,327	<b>Applicant(s)</b> MURPHY, PATRICIA D.	
	<b>Examiner</b> Carla Myers	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 97-124 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 97-124 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

1. The amendment filed on September 17, 2003 canceling all claims drawn to the examined invention and presenting only claims drawn to a new invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the originally presented invention and are subject to the restriction requirement that follows.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 97-121, drawn to methods for determining a haplotypes of BRCA1 by comparing a nucleic acid sequence from a female individual with a family history of breast cancer to a BRCA1 nucleotide sequence, classified in Class 435, subclass 6.

II. Claims 122-124, drawn to methods for determining a haplotypes of BRCA1 by comparing a nucleic acid sequence from a female individual with a family history of breast cancer to a MSH2 nucleotide sequence, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to patentably distinct methods. The inventions require determining a haplotypes by comparing an individual's nucleic acid sequence to distinct nucleic acid sequences. In particular, the method of invention I requires comparing an individual's nucleic acid sequence to the sequence of BRCA1 (SEQ ID NO: 263 or the nucleic acid encoding SEQ ID NO: 264). Invention II requires comparing an individual's nucleic acid sequence to the sequence of MSH1 (SEQ ID NO: 1 or 2; see page 23 of the specification). BRCA1 and MSH1 are structurally and functionally distinct genes. Accordingly, the methods of inventions I and II are patentably distinct from each other because these methods require analyzing structurally and functionally

distinct nucleic acids and involve determining haplotypes that are also structurally and functionally distinct.

### **3. Sequence Election Requirement Applicable to Invention I**

In addition, claims 102 and 104 of invention I read on patentably distinct inventions drawn to multiple SEQ ID Numbers. The 22 sequences set forth in Table 9 are patentably distinct because they each consist of a distinct nucleotide sequence, and a further restriction is applied to each invention. Applicants must further elect a single nucleic acid selected from the group consisting of SEQ ID NO: 171-192.

It is noted that nucleotide are structurally distinct chemical compounds and each has a distinct functional property in that it hybridizes to a different region of BRCA1 and amplifies or detects distinct nucleic acids. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species. While claims 97-101, 103, and 105-121 will be examined for their full scope, claims 102 and 104 will be examined only to the extent that they read on the elected sequence.

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4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as recognized by their divergent subject matter and because inventions I and II require different keyword and sequence searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

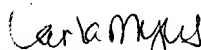
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. This phone number will be changed after January 13 to (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers  
December 9, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER